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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/560,181 | 12/09/2005 | Gitte Juel Friis | P70948US0 | 1455 |

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| EXAMINER | |
|---|---|
| FOLEY, SHANON A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1619 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/560,181 | FRIIS ET AL. | |
| | Examiner | Art Unit | |
| | SHANON A. FOLEY | 1619 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,5-15,19,20,27,28,30-37 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-15,19,20,27,28,30-37 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's arguments are found persuasive with regard to the teachings of Cleary et al. (USPgPub 2003/0170308). However, an updated search revealed pertinent prior, necessitating new grounds of rejection.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-7, 19, 20, 27, 28, 30, 32-37 and 39 are rejected under 35 U.S.C. 103(a) as being obvious over Qvist (USPgPub 2007/0009583) and Zhang et al. (USPgPub 20050276842).

Qvist teaches a sheet-like foam wound care device comprising an absorbent layer, an active pain relieving agent, ibuprofen, incorporated into and/or onto a wound-contacting layer that is easily removable from a wound, see paragraphs [0001, 0018, 0019, 0027, 0030, 0036, 0042], Example 2A described in paragraph [0045] and claims 1 and 5. The dressing of Qvist releases the pain-relieving agent at the site of the wound or at different areas of the wound, see paragraph [0042] and is present in a quantity less than a systemic treatment dose. The device of Qvist is explicitly taught to have a maximum absorption of 0.1 $g/cm^2$, 0.05 $g/cm^2$, 0.075 $g/cm^2$ to promote moist wound-healing, see paragraph [0021, 0024]. Qvist also teaches that the device is in the form of a fabric, see paragraphs [0019, 0023] and further comprises a debriding enzyme as a non-stick agent in combination with the pain-killing agent, see paragraph [0042].

The thickness of the device of Qvist is taught to be 3 mm, see paragraph [0045]. Therefore, Qvist does not teach a wound care device having a thickness ranging between 0.5 mm to 1.5 mm. Qvist also does not teach petroleum as a non-stick agent.

Zhang et al. teach a device for dermal delivery of NSAIDs, which also comprises petrolatum, and is between 0.05 to 1 mm thick, see claims 1, 6, 11, 15, 56-58, 60, 66, 99, 101, 103 and 109.

One of ordinary skill in the art at the time the invention was made would have been motivated to modify the thickness of the device of Qvist to between 0.5 to 1.0 mm thick to enhance comfort of the patient. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success to lessen the thickness of the device of Qvist to the thickness of Zhang et al. since both dermal devices of Qvist and Zhang et al. deliver NSAIDs, see paragraph [0036] of Qvist and claims 15, 66 and 109 of Zhang et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to incorporate the petrolatum of Zhang et al. into the device of Qvist to reduce irritation and/or prevent the device from sticking to the wound. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for incorporating the petrolatum of Zhang et al. into the device of Qvist because Qvist incorporates debridement enzymes to inhibit attachment of the device.

Claims 8-15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qvist and Zhang et al. as applied to claims 1, 3, 5-7, 19, 20, 27, 28, 30, 32-37 and 39 above, and further in view of Edgren et al. (US 6,245,357).

The instant claims state that the release rate of the pain-relieving agent is at least 50, 75 or 90% during the first 6, 12 or 24 hours after application of the wound device.

See the teachings of Qvist and Zhang et al. above. Qvist teach that the release rate of the enzyme, papain, is 95% within 24 hours, 36 hours and 12 hours, respectively, see Examples 2B, 2D and 3B. Zhang et al. teach that the dermal delivery device releases NSAIDs at a constant release rate for at least 4, 8 and 12 hours, see claims 1 and 30-32. However, neither Qvist nor Zhang et al. teach the rate of release of the pain-relieving agent instantly claimed.

However, Edgren et al. teach a release rate of an analgesic ranging between 55, 75 and 100% during the first 8, 12 and 24 hours after application of a , see claims 10, 46, 50, 51, 59 and 60.

One of ordinary skill in the art at the time the invention was made would have been motivated to alter the quantity of analgesic drug released from a wound device, depending on the severity of the wound and the duration for pain relief required. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for altering the rate of analgesic release in the dermal release device of Qvist and Zhang et al. in the wound care system of Edgren et al. since all of the wound care devices administer the pain-relief agents through dermal delivery devices, see the previous citations of Qvist and Zhang et al. and claims 28 and 36-38 of Edgren et al.

**Response to Arguments**

With regard to the teachings of Edgren et al., applicant argues that the Office does not provide any motivation for combining the oral dosage form of Edgren et al.

Applicant's arguments have been fully considered, but are found unpersuasive. The membrane system claimed by Edgren et al. in claim 28 is not limited to an oral dosage form (emphasis added).

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on flex, generally M-F 7AM - 3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/
Primary Examiner
Art Unit 1619